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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,149	01/19/2001	Eberhard Nieschlag	PLOVIN-3A	8178

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EXAMINER

BENNETT, RACHEL M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/764,149

Applicant(s)

NIESCHLAG ET AL.

Examiner

Rachel M. Bennett

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 57-129 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-129 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

The Examiner acknowledges receipt of Amendment B filed 5/21/02 and Supplemental Amendment C filed 5/28/02.

Claims 57-129 are pending.

### *Specification*

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 57-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guerin et al.

Guerin discloses the combination of progestagens and androgens and its use for male contraception (see abstract and entire article). The reference teaches progestagens such as medroxyprogesterone acetate and norethisterone and androgens such as testosterone and testosterone undecanoate (see page 188, lines 14-22). The reference also teaches (1) both steroid classes can be administered by intramuscular injections; (2) azoospermia or oligozoospermia are obtained (see page 188, lines 4-8) and (3) the use of various amount of each active agent.

The instant claims differ from the reference by reciting various dosages of the active ingredient(s). However, the preparation of various pharmaceutical formulations having various amounts of the active agent is within the level of skill of one having ordinary skill in the art at

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the time of the invention. It is also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

### ***Response to Arguments***

#### ***Rejection under 35 U.S.C. 102 and 35 U.S.C. 103 over Guerin***

3. Applicant's arguments filed 5/21/02 have been fully considered but they are not persuasive. Applicants argue Guerin fails to teach non-oral administration. Also Guerin also teaches oral administration is the preferred administration route. It is the position of the examiner that while Guerin prefers oral administration, it is not the only mode of administration disclosed. Furthermore, Applicants themselves disclose on page 11 of the instant specification, while the method of preferred method of administration is by non-oral means, the method of administration is a means to an end, that is to say a method of delivering the formulation in any of its embodiments at an effective level, other methods of administration are anticipated. Therefore, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the mode of delivery based on the population, age, indented dose and length of administration.

Applicants also claim Guerin only teaches daily administered hormones, thus, the hormones would not be provided in amount such that upon administration effective levels in the blood that are sustained for not less than 1 week. The examiner refers to instant claim 76 wherein, "the effective amounts of said androgen and said NET derivatives are such that the effective levels in blood are sustained for not less than 1 week". Guerin discloses the administration of the hormone daily, wherein the protocols are disclose the daily administration

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of 0-3 months, 3-6 months and 6-18 months. Therefore, the daily administration of hormone would sustain the hormone in the blood for not less than 1 week as claimed by Applicant. The rejection is maintained.

***Rejection under 35 U.S.C. 102 and 35 U.S.C. 103 over Spona***

4. Applicant's arguments filed 5/21/02 have been fully considered and are found to be persuasive. Therefore, the rejection has been withdrawn.

***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 309-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett: RMB  
August 9, 2002

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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